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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/288,837 04/08/99 MACDONALD G 5470-238

020792 HM12/0330
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EXAMINER

BRUMBACK, B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED:

03/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/288,837

Applicant(s)
MacDonald et al.

Examiner
Brenda Brumback

Group Art Unit
1642



☒ Responsive to communication(s) filed on Feb 22, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3, 5-8, 11, 12, and 15-94 is/are pending in the application.

Of the above, claim(s) 17-83 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 5-8, 11, 12, 15, 16, and 84-94 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

DETAILED ACTION

1. This action is responsive to the amendment filed 02/22/2001. Claims 4, 13, and 14 were canceled. Claims 1, 16, and 84 were amended. New claims 85-94 were added. Claims 1-3, 5-8, 11, 12, and 15-94 are pending. Claims 1-3, 5-8, 11, 12, 15, 16, and 84-94 are under examination.
2. This application contains claims 17-83 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

3. The objection to claims 1 and 84 is withdrawn pursuant to applicant's amendment thereof.

Claim Rejections - 35 USC § 112

4. The rejection of claims 1-8, 11-15, and 84 under 35 U.S.C. 112, second paragraph, is withdrawn pursuant to applicant's cancellation of claim 13 and arguments, which were persuasive.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Applicant argues that one of ordinary skill in the art at the time of the invention would have had no reasonable expectation of success in achieving the present invention; however, applicant has provided no reasons or evidence in support of this statement. Argument in the absence of evidence is not persuasive.

Applicant argues that the present inventors have unexpectedly found that alphavirus vectors are effective in providing protection against tumor establishment and in causing regression of established tumors; however, no reasoning or evidence to support this argument has been provided. Absent some evidence to the contrary, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation that an artificial cancer antigen delivered via an alphavirus vector would have provided an effective prophylactic and therapeutic method of anti-tumor immunization because Falo et al. specifically teaches the effectiveness of cells tagged with an artificial cancer antigen (see the first sentence of the abstract) and Johnston et al. teaches alphavirus vectors for effective intracellular delivery of an antigen to cells (see page 11, line 22 and page 14, lines 9-16).

Applicant argues that Johnston et al. does not describe alphavirus vectors expressing a helper T cell epitope, a cytotoxic T cell epitope, a T-dependent B cell epitope or a T independent B cell epitope as recited in claim 1. Applicant is referred to the paragraph bridging pages 1 and 2, wherein Johnston et al. suggest that VEE virus constructs comprising heterologous antigen might be used to produce protective B and T cell mediated immunity, and to examples 6 and 7 (pages 14-15) wherein Johnston et al. teach successful protection of immunized mice against influenza

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viral challenge by immunizing with an alphavirus vector comprising the heterologous influenza viral antigen. These teachings lead directly to alphavirus vectors comprising the claimed epitopes. Additionally, Falo et al. specifically teach a cytotoxic T cell immune response to artificial cancer antigen when tumor cells are tagged with an artificial cancer antigen (see the abstract).

With respect to new claim 94, applicant argues that neither Johnston nor Falo disclose or suggest the desirability of using a cell-surface protein or peptide as an artificial cancer antigen. The examiner disagrees. Falo et al. teach engineering tumor cells to present an artificial cancer antigen on the cell surface. Falo et al. then teach that, due to cross-priming, the tagged tumor cells focus the immune response on host tumor cells in a manner sufficient to stimulate CTL-mediated immunity to multiple, additional tumor antigens present on the unmodified host tumor cell surface (see column 3, lines 53-65).

Conclusion

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after


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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

March 29, 2001


Brenda Brumback,
Patent Examiner



Creation date: 12-20-2003
Indexing Officer: EALVAREZ - ELMO ALVAREZ
Team: OIPEBackFileIndexing
Dossier: 09288837

Legal Date: 07-18-2001

No.	Doccode	Number of pages
1	EXIN	2

Total number of pages: 2

Remarks:

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